

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

**CAROLYN ANTALOCY,**

**Case No.: 4:23-cv-02098**

**Plaintiff,**

**-vs-**

**JUDGE PAMELA A. BARKER**

**SANOFI US SERVICES INC., et al.,**

**Defendants.**

**MEMORANDUM OPINION & ORDER**

Before the Court is Plaintiff Carolyn Antalocy’s (“Antalocy”) Motion for Leave to Amend Complaint filed on January 31, 2024. (Doc. No. 21.) On February 14, 2024, Defendants Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC (together, “Sanofi”) filed an Opposition (Doc. No. 22), to which, on February 28, 2024, Antalocy filed a Reply. (Doc. No. 23.)

For the following reasons, the Court DENIES Antalocy’s Motion for Leave to Amend.

**I. Background**

**A. Procedural History**

Antalocy’s action is one of thousands filed in a multidistrict litigation (“MDL”) in the Eastern District of Louisiana, *In re: Taxotere (Docetaxel) Products Liability Litigation*, MDL No. 16-2740, and one of hundreds that the MDL court recently transferred to district courts around the country for further proceedings. (See Doc. No. 7.) Antalocy and the other MDL plaintiffs sued Sanofi and others that manufactured and distributed the chemotherapy drug Taxotere (or docetaxel, its generic version).

(*Id.* at p. 73<sup>1</sup>.) They allege that the drug caused permanent chemotherapy induced alopecia (“PCIA”).

(*Id.* at p. 73-74.)

On March 31, 2017, the MDL plaintiffs filed a Master Complaint. (*Id.* at p. 74.) Shortly thereafter, the MDL plaintiffs filed a First Amended Complaint to correctly name certain defendants. (*Id.*) The defendants moved to dismiss the First Amended Complaint, which the MDL court granted in part, dismissing two of the plaintiffs’ claims for strict product liability and breach of express warranty. (*Id.* at p. 74-75.) As to these two claims, the MDL court ruled that “specific allegations . . . of fraud should be perfected within the short form complaints filed in the individual member cases.” (Doc. No. 22-1, PageID# 489.) The MDL court gave the plaintiffs until October 11, 2017, to add specific allegations of fraud that would support state law claims for strict liability and breach of express warranty to their short form complaints. (Doc. No. 6-2, p. 121.)

On September 17, 2018, the MDL plaintiffs filed a Second Amended Master Complaint. (*Id.* at p. 75.) This master complaint is identical to the first but adds an additional defendant. (Doc. No. 6-2, p. 150.) The Second Amended Master Complaint “remains the operative pleading” in this case. (Doc. No. 7, p. 75.)

Relevant here, the Second Amended Master Complaint defines PCIA “as an absence of or incomplete hair regrowth **six months beyond the completion of chemotherapy.**” (Doc. No. 6-4, pp. 37-38, ¶ 181<sup>2</sup> (emphasis added).) On December 12, 2019, the MDL plaintiffs moved to amend this definition to read that:

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<sup>1</sup> The Court will refer to pages in the MDL’s Transfer Order (Doc. No. 7) by the page numbers at the bottom of the Order, numbering from 1 to 126, as the header with the PageID number is obscured on many pages.

<sup>2</sup> Like the Transfer Order, the PageID numbers in the Joint Designation of Record for MDL Transfer (Doc. No. 6) are obscured. Accordingly, the Court will refer to pages in the Joint Designation of Record by their numeric order in the

There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient, including among Plaintiffs. The scientific literature has variously referred to Permanent Chemotherapy Induced Alopecia as occurring between twelve to twenty-four months following chemotherapy treatment. Some literature has indicated that hair loss can be deemed “persistent” six months beyond the completion of chemotherapy.

(*Id.* at p. 458, ¶ 194.) The MDL court denied the plaintiffs’ motion. The court reasoned that “[t]he parties and the Court have been operating under Plaintiffs’ original definition” of PCIA since March 31, 2017, when the plaintiffs filed their original master complaint.” (*Id.* at pp. 1427-28.) To allow the plaintiffs to amend that definition now, the MDL court continued, “would negate a significant amount of the work that has been done in this MDL.” (*Id.* at p. 1428.) The MDL court concluded that “the main reason Plaintiffs wish to amend . . . at this juncture is to save cases that are otherwise subject to dismissal for being filed too late,” which “would cause serious prejudice to Defendants.” (*Id.* at pp. 1428-29.)

In addition to the master complaint, each MDL plaintiff, including Antalocy, filed a short form complaint. (See Doc. No. 1.) The individual short form complaints contain “[p]laintiff-specific allegations” and incorporate by reference the allegations and claims in the Second Amended Master Complaint. (Doc. No. 7, p. 75.) After the MDL court denied the MDL plaintiffs’ motion to amend the definition of PCIA in the Second Amended Master Complaint, three plaintiffs<sup>3</sup> moved to revise the definition of PCIA in their short form complaints. (Doc. No. 6-4, pp. 1431-32.) The MDL court

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document. For example, Document Number 6-4 is numbered 1 through 1,470, with pages 2 through 68 containing the Second Amended Master Complaint.

<sup>3</sup> The MDL court selected these three plaintiffs “to proceed with discovery in connection with the third bellwether trial.” (Doc. No. 6-4, pp. 1431-32.)

denied their individual motions for the same reasons it denied the plaintiffs' motion to amend the Second Amended Master Complaint. (*Id.* at p. 1433.)

On May 11, 2020, in response to the "many" MDL plaintiffs that sought to amend their short form complaints "as they relate to statute of limitations," the MDL court issued Pretrial Order 105 ("PTO 105") permitting the plaintiffs to amend their complaints "to add factual allegations regarding particularized facts individual and specific to each Plaintiff's medical care and treatment and/or Plaintiff's communications with medical professionals." (Doc. No. 6-2, p. 167.) The final deadline for the MDL plaintiffs to make these amendments was January 15, 2021. (*Id.* at p. 169.) In its Order transferring Antalocy's case to this Court, the MDL court declared that "[a]ll deadlines for Plaintiffs to amend their individual complaints without leave of court has passed." (Doc. No. 7, p. 76.)

Antalocy filed her short form complaint in the MDL on October 4, 2017. (Doc. No. 1.) She alleges that she used Taxotere from between approximately April 11, 2008, through July 3, 2008. (*Id.* at PageID# 3-4.) Beyond the claims she adopts from the Second Amended Master Complaint, Antalocy adds claims for "Extreme and Outrageous Conduct / Intentional Infliction of Emotional Distress" and for punitive damages. (*Id.* at PageID# 4-5.) Her short form complaint does not contain any particularized facts as to her medical care and treatment or her communications with medical professionals.

The MDL court transferred Antalocy's case to this Court on October 23, 2023. (Doc. No. 7, p. 1.) On December 12, 2023, the Court held a Case Management Conference and set case deadlines. (Doc. Nos. 19, 20.) Specifically, the Court set January 31, 2024, as the deadline for Antalocy to file a motion for leave to amend her complaint. (Doc. No. 20.)

On January 31, 2024, Antalocy filed her Motion for Leave to Amend Complaint. (Doc. No. 21.) She attached to her Motion her proposed Amended Complaint. (Doc. No. 21-1.) On February 14, 2024, Sanofi filed an Opposition to Antalocy's Motion. (Doc. No. 22.) And, on February 28, 2024, Antalocy filed a Reply in support of her Motion. (Doc. No. 23.)

#### **B. Allegations in Proposed Amended Complaint**

In her proposed Amended Complaint, Antalocy seeks to add the following allegations.

First, she moves to amend the definition of PCIA to read:

There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient. The scientific literature has variously referred to Permanent Chemotherapy Induced Alopecia as occurring between twelve to twenty-four months following chemotherapy treatment. Some literature has indicated that hair loss can be deemed “persistent” six months beyond the completion of chemotherapy.

(Doc. No. 21-1, ¶ 102.)

Second, she moves to add a claim for “Non-Conformance with Representations” under Ohio Revised Code Section 2307.77. (*Id.* at ¶¶ 180-187.) This claim generally alleges that Sanofi “misrepresented facts . . . concerning the character or quality of” Taxotere, which Antalocy “and/or her healthcare providers reasonably relied on.” (*Id.* at ¶¶ 183, 185.)

Third, Antalocy moves to add specific allegations regarding fraud and the statute of limitations. (*Id.* at ¶¶ 157-166.) She alleges that her oncologist informed her “that hair loss from chemotherapy would be temporary in nature.” (*Id.* at ¶ 159.) And she was never told that Taxotere may result in permanent hair loss. (*Id.* at ¶ 160.) If she had been informed of the risk of permanent hair loss, she alleges, “she would have asked for a different treatment option.” (*Id.* at ¶ 161.) Finally, she seeks to allege that she “did not learn that Taxotere causes permanent hair loss until she saw a legal advertisement in 2016.” (*Id.* at ¶ 164.) After seeing this advertisement, she “sought legal

counsel to investigate her potential claim,” leading to her filing a complaint in the MDL in October 2017—“well within Ohio’s two-year statute of limitations.” (*Id.* at ¶ 165.)

## **II. Law and Analysis**

As just summarized, Antalocy seeks to amend her Complaint in three ways: (1) by revising the definition of PCIA, (2) by adding a claim for non-conformance with representations under Ohio law; and (3) by adding specific allegations regarding fraud and the statute of limitations. But in her Reply, Antalocy agrees to withdraw her claim for non-conformance with representations based on the MDL court’s prior rulings. (Doc. No. 23, PageID# 623.) Therefore, the Court will only consider her proposed amendments to revise PCIA’s definition and to add allegations regarding fraud and the statute of limitations, in that order.

### **A. Proposed Amendment to Revise the Definition of PCIA**

As to Antalocy’s request to amend the definition of PCIA, Sanofi argues that the law-of-the-case doctrine means that this Court should not “revisit[] the MDL court’s prior order denying an identical request to amend in the MDL.” (Doc. No. 22, PageID# 474.) Specifically, Sanofi contends that the MDL court’s ruling was not “clearly erroneous or manifestly unjust.” (*Id.*) Further, Sanofi asserts that amending the PCIA definition now would make the MDL court’s work “meaningless” and would, “[i]n effect,” require the litigation in this case to “begin anew.” (*Id.* at PageID# 479.) Finally, Sanofi notes that “[c]ourts in other jurisdictions considering similar requests have uniformly rejected them.” (*Id.*)

Antalocy denies that her proposed amendment is the identical request that the MDL court ruled on. (Doc. No. 23, PageID# 620.) And she contends that her proposed definition of PCIA is only meant to address “vagueness and inaccurate science surrounding one paragraph” in the Second

Amended Master Complaint. (*Id.* at PageID# 621.) She further contends that her amendment will make PCIA’s definition in her Complaint “consistent with medical science” and “with discovery and testimony adduced in the case.” (*Id.* at PageID# 623.)

For the following reasons, the Court agrees with Sanofi that Antalocy’s Motion for Leave to Amend the PCIA definition effectively asks that the Court revisit the MDL court’s order denying the same.

Under the law-of-the-case doctrine, “a decision on an issue made by a court at one stage of a case should be given effect in successive stages of the same litigation.” *United States v. Todd*, 920 F.2d 399, 403 (6th Cir. 1990) (citing *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816, (1988)). The doctrine “promotes judicial efficiency by prohibiting parties from indefinitely relitigating the same issue that a court resolved in an earlier part of the case.” *Samons v. National Mines Corp.*, 25 F.4th 455, 463 (6th Cir 2022).

A court can revisit a prior decision, but only “(1) where substantially different evidence is raised on subsequent trial; (2) where a subsequent contrary view of the law is decided by the controlling authority; or (3) where a decision is clearly erroneous and would work manifest injustice.” *Hanover Ins. Co. v. Am. Eng’g Co.*, 105 F.3d 306, 312 (6th Cir. 1997). This is true in the MDL context as well. The Sixth Circuit has held that “as a practical matter” the transferee court “ought . . . to accord considerable deference to the judgment of the transferor court.” *In re Upjohn Co. Antibiotic Cleocin Prods. Liab. Litig.*, 664 F.2d 114, 120 (6th Cir. 1981).

On December 12, 2019, the MDL court denied the plaintiffs’ motion to amend the Second Amended Master Complaint to no longer define PCIA as an injury that manifests six months after chemotherapy. (*See* Doc. No. 7, p. 75.) The MDL court decided that the plaintiffs’ proposed

amendment would “negate a significant amount of work that has been done in this MDL” and the defendants “would undoubtedly want to revise certain expert reports and conduct supplemental depositions, and certain rulings from the Court would be mooted.” (Doc. No. 6-4, p. 1428.) The MDL court reasoned that it “w[ould] not allow Plaintiffs to make these unduly belated amendments that would cause serious prejudice to Defendants.” (*Id.* at p. 1429.) It concluded that “Plaintiffs made an informed decision to define their injury the way they originally did” and it would “not allow Plaintiffs at this point in the MDL to backtrack on that decision.” (*Id.*)

Antalocy now seeks to revise the definition of PCIA in her Complaint using the *exact same* language that the MDL plaintiffs unsuccessfully moved to use. In her Reply, Antalocy writes that Sanofi is “simply incorrect that the instant proposed amended pleading is the ‘exact request’ that was denied in 2019.” (Doc. No. 23, PageID# 620.) But Antalocy misrepresents the record in this case. In December 2019, the MDL plaintiffs moved to revise the PCIA definition to read:

There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient, **including among Plaintiffs**. The scientific literature has variously referred to Permanent Chemotherapy Induced Alopecia as occurring between twelve to twenty-four months following chemotherapy treatment. Some literature has indicated that hair loss can be deemed “persistent” six months beyond the completion of chemotherapy.

(Doc. No. 6-4, p. 458, ¶ 194 (emphasis added).) Antalocy’s proposed amended definition would read:

There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient. The scientific literature has variously referred to Permanent Chemotherapy Induced Alopecia as occurring between twelve to twenty-four months following chemotherapy treatment. Some literature has indicated that hair loss can be deemed “persistent” six months beyond the completion of chemotherapy.

(Doc. No. 21-2, ¶ 102.) Antalocy’s proposed amendment differs only in that it deletes the bolded words “including among Plaintiffs” in the first sentence. Notwithstanding Antalocy’s assertion to the

contrary, the MDL court ruled on the “exact request” that Antalocy now makes. This Court must therefore give the MDL court’s “judgment” on this issue “considerable deference.” *In re Upjohn Co.*, 664 F.2d at 120. Antalocy has offered no argument that the MDL court’s ruling is “clearly erroneous and would work a manifest injustice.” *Christianson*, 486 U.S. at 817. In denying the plaintiff’s motion for leave to amend the definition of PCIA, the MDL court applied Rule 15(a)(2) and considered the relevant factors. (Doc. No. 6-4, p. 1426-27.) Most importantly, the MDL court concluded that the revised definition “would cause serious prejudice to Defendants.” (*Id.* at p. 1429.) This Court sees no cause to revisit the MDL court’s decision. So, consistent with the other court in the Sixth Circuit which has considered this issue, this court denies Antalocy’s Motion for Leave to Amend the PCIA definition in her Complaint. *See Jackson v. Sanofi-Aventis U.S. LLC*, 2024 U.S. Dist. LEXIS 48896 at \*17 (M.D. Tenn. Jan. 29, 2024) (“Plaintiffs have failed to demonstrate that the MDL Court’s ruling . . . was either ‘clearly erroneous’ or would ‘work a manifest injustice.’”).

#### **B. Specific Allegations Regarding Fraud and the Statute of Limitations**

Sanofi opposes on different grounds the part of Antalocy’s Motion that seeks to add specific allegations regarding fraud and the statute of limitations. Sanofi argues that the MDL court set a deadline for plaintiffs to amend their short form complaints with specific fraud allegations in PTO 105, and, since that deadline has long passed, Antalocy must demonstrate “good cause” under Rule 16 for her proposed amendments, which she fails to do. (Doc. No. 22, PageID# 481.) In Reply, Antalocy contends that the MDL parties stipulated that:

Sanofi would not argue untimeliness or waiver of amendment if MDL plaintiffs chose not to challenge the limitation of PTO 105 by filing a contested amendment to add allegations beyond what PTO 105 would allow (i.e., PTO 105 only allowed addition of “factual allegations regarding particularized facts individual and specific to each Plaintiff’s medical care and treatment and/or that Plaintiff’s communications with

medical professionals’’). Indeed, as the Stipulation notes, plaintiffs disagreed with the limitations the MDL Court placed on amendments in PTO 105.

(Doc. No. 23, PageID# 624.) Antalocy appears to argue that Sanofi either waived the right to oppose her instant Motion, or that PTO 105 did not actually set a deadline for the specific allegations she now seeks to add.

For the following reasons, the Court concludes that PTO 105 did set a deadline for Antalocy’s proposed amendments, and that she has failed to demonstrate good cause to modify that deadline.

The MDL court issued PTO 105 because “many Plaintiffs [had] begun amending . . . their individual Short Form Complaints in response to [the MDL court’s] rulings on recent motions seeking to amend pleadings as they relate to statute of limitations.” (Doc. No. 6-2, p. 167.) In the Order, the MDL court permitted the plaintiffs to “amend their complaints to add factual allegations regarding particularized facts individual and specific to each Plaintiff’s medical care and treatment and/or Plaintiff’s communications with medical professionals.” (*Id.*) On October 23, 2020, the parties entered into a stipulation extending the deadline for the MDL plaintiffs to make these amendments to January 15, 2021. (*Id.* at p. 169.) This stipulation also provided that “[i]f a Defendant seeks dismissal of any case based on a statute of limitations, it agrees that it will not argue waiver based on any Plaintiff’s refraining from amending her [short form complaint] to include allegations inconsistent with PTO 105.” (*Id.*)

The Court reads PTO 105 to have set a deadline for Antalocy to amend her short form complaint in the MDL with the specific allegations she now seeks to add to her Complaint in this case. That deadline has now passed. (See Doc. No. 7-2, p. 76 (the MDL court noted that “[a]ll deadlines for Plaintiffs to amend their individual complaints without leave of court have passed” and cited PTO 105).) The stipulation to PTO 105 narrowly limited the arguments Sanofi could make in

a motion to dismiss based on a statute of limitations. But since Sanofi is not “seek[ing] dismissal of [this] case based on a statute of limitations,” that clause is not at issue here.

As PTO 105 set a deadline for amendments, Antalocy must demonstrate “good cause” to modify that deadline. Fed. R. Civ. P. 16(b)(4); *Leary v. Daeschner*, 349 F.3d 888, 909 (6th Cir. 2003). A court primarily measures “good cause” under Rule 16 by considering two factors: (1) “the moving party’s diligence in attempting to meet the case management order’s requirements,” and (2) “possible prejudice to the party opposing the modification.” *Inge v. Rock Fin. Corp.*, 281 F.3d 613, 625 (6th Cir. 2002). Both factors weigh against Antalocy.

First, Antalocy offers little argument why she did not amend her complaint before PTO 105’s deadline. In her Motion, she writes that “[i]n [her] opinion, PTO 105 unnecessarily and improperly limited the ability of the plaintiffs to allege case specific facts without conducting the necessary analysis of whether to grant leave under Rule 15.” (Doc. No. 21-1, PageID# 402.) But PTO 105 explicitly permitted the plaintiffs to allege specific facts regarding their medical care and communications with medical professionals. Antalocy fails to explain what other “case specific facts” she is referring to. Indeed, the allegations she seeks to add in her proposed Amended Complaint are precisely about her medical care. For example, she seeks to allege that she “received Taxotere in combination with Carboplatin and Herceptin from April to July of 2008 as part of her breast cancer treatment.” (Doc. No. 21-2, ¶ 157.) And she seeks to allege that she “was informed by her prescribing oncologist that hair loss from chemotherapy would be temporary in nature.” (*Id.* at ¶ 159.) PTO 105 would have permitted these amendments. Moreover, the allegations she seeks to add were known to her well before she filed suit in the MDL. *See, e.g., Daddino v. Sanofi US Servs. Inc.*, 2024 U.S. Dist. LEXIS 47703 at \*27-28 (E.D.N.Y. Mar. 18, 2024) (analyzing similar proposed allegations and

concluding that “[t]hese are precisely the kind of facts contemplated by PTO 105 . . . , and, therefore, Plaintiff was required to allege these facts by January 15, 2021”). Antalocy was not diligent in amending her individual complaint within PTO 105’s deadline. This factor thus weighs against her.

Second, Antalocy argues that her proposed amendments would not prejudice Sanofi because it “has not yet been required to file a case-specific answer, discovery has not begun, and Plaintiff has yet to give her deposition testimony.” (Doc. No. 21-1, PageID# 403.) Her argument ignores the fact that Sanofi filed a Master Answer in the MDL (Doc. No. 6-4, p. 246), which, when filed, the MDL court “deemed to have answered all cases pending in, filed in, or subsequently transferred to the MDL.” (Doc. No. 6-2, p. 16.) Moreover, the parties in the MDL completed “all general fact and expert discovery,” such that the receiving courts “need not be concerned with facilitating general expert, corporate, and third-party discovery.” (Doc. No. 7, p. 116.) While some discovery remains, its scope is limited. (*Id.* at p. 117.) The purpose of the MDL was to “eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel, and the judiciary.” (*Id.* at pp. 1-2.) Many of the MDL court’s pretrial rulings concerned the statute of limitations, an issue Antalocy’s proposed amendments would directly affect. (*See id.* at pp. 95-99.) Allowing Antalocy to amend her Complaint at this late stage would undo much of the MDL court’s work and, in the process, prejudice Sanofi. *See, e.g., Jackson*, 2024 U.S. Dist. LEXIS 48896 at \*31 (“allowing Plaintiffs to amend at this stage would nullify the work of the MDL Court”). This factor also weighs against Antalocy.

Since both factors weigh against Antalocy, she has failed to demonstrate good cause under Rule 16. Accordingly, the Court denies her Motion for Leave to Amend to add specific allegations regarding fraud and the statute of limitations.

**III. Conclusion**

For the foregoing reasons, the Court DENIES Antalocy's Motion for Leave to Amend Complaint. (Doc. No. 21.)

**IT IS SO ORDERED.**

Dated: March 28, 2024

*s/ Pamela A. Barker*  
PAMELA A. BARKER  
UNITED STATES DISTRICT JUDGE